K130337

JUN 19 2013

510(k) Summary

Date of Preparation: 22nd January 2013

1. SAFETY AND EFFECTIVENESS AS REQUIRED BY 21 CFR 807.92 STATEMENT

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92.

2. SUBMITTER NAME AND ADDRESS

Name: Randox Laboratories Limited

Address: 55 Diamond Road, Crumlin,
County Antrim, BT29 4QY,
United Kingdom.

Telephone: +44 (0) 28 9442 2413
Fax: +44 (0) 28 9445 2912
E-mail: marketing@randox.com

3. 510k NUMBER, DEVICE PROPRIETARY NAME, COMMON NAME, PURPOSE FOR SUBMISSION, REGULATORY CLASSIFCATION, PANEL, PRODUCT CODE AND 21 CFR NUMBER

510k No: Not known

Device Proprietary Name: Randox Immunoassay Speciality Control (I) Levels 1, 2 and 3

Common Name: Immunoassay Speciality Control (I) Levels 1, 2 and 3

Purpose for Submission: New Device

Regulatory Classification: Multi-analyte Controls, All kinds (Assayed and Unassayed)

Panel: Clinical Chemistry

Product Code: JJY

21 CFR Number: 21 CFR 862.1660

4. PREDICATE DEVICE PROPRIETARY NAMES AND 510 (k) NUMBERS

Predicate Device Proprietary Name:
BIO-RAD Liquichek™ Speciality Immunoassay Control Levels LTA Levels 1, 2 and 3.

510 (k) Number: K043108

5. INTENDED USE

The Randox Immunoassay Speciality Control (I) Levels 1, 2 and 3 are intended for in vitro diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. This device is for prescription use only.

6. DEVICE DESCRIPTION

Randox Immunoassay Speciality Control (I) is manufactured at three levels, Level 1, Level 2 and Level 3.
Each control is prepared from human serum with added constituents of human origin, chemicals, stabilizers and preservatives. They are supplied in lyophilised form in 5x2ml vials and require reconstitution with 2ml of distilled water.

The analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision level(s). The analyte concentrations have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

7. PREDICATE DEVICE COMPARISON TABLE

CHARACTERISTICS	RANDOX SPECIALITY IMMUNOASSAY CONTROL (I) LEVELS 1, 2 AND 3	BIO-RAD LIQUICHEK ™ SPECIALTY IMMUNOASSAY CONTROL LTA LEVELS 1, 2 & 3 K043108
INTENDED USE	The Randox Immunoassay Speciality Control (I), levels 1, 2 & 3 are intended for in vitro diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	For use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert
SIZE	2ml	5ml
FORMAT	Lyophilised	Liquid
MATRIX	Human Serum	Human Serum
STORAGE (Unopened)	2 to 8 °C Until expiration date	-20 to -70°C Until expiration date
OPEN VIAL CLAIM	Store refrigerated +2 to 8°C Reconstituted serum is stable for 5days at +2 to 8°C if kept capped in original container or 4weeks frozen once at -20°C. Anti-TG is stable for 3days at +2 to 8°C. C-Peptide, IGF-I and Procalcitonin are stable for 1day at +2 to 8°C. Osteocalcin is stable for 4hours at +2 to 8°C and Parathyroid hormone should be tested within 4hours of reconstitution when stored at +2 to 8°C or within 2weeks when stored below -20°C.	Once the product is thawed and opened, all analytes will be stable for 30days when stored tightly capped at 2-8°C with the exception of PTH which will be stable for 23days. PTH, Anti-TG and Anti TPO will be stable for 30 days when stored in tightly capped aliquot vials at -20°C to -70°C.
SHIPPING TEMPERATURE	+2 to 8°C	-20 to -70°C
ANALYTES	1-25 OH Vitamin D, 25 OH Vitamin D, Anti TG, Anti TPO, C-Peptide, Insulin Like Growth Factor (IGF 1), Osteocalcin, Parathyroid Hormone (PTH) Insulin	Anti-Thyroglobulin (Anti-TG) Anti-Thyroperoxidase (Anti-TPO) C-Peptide Insulin Like Growth Factor I (IGF-I) Intact Parathyroid Hormone (Intact-PTH) 25-OH Vitamin D Osteocalcin

8. SUMMARY OF STABILITY STUDIES

Opened: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 5 days at +2°C to +8°C if kept capped in the original container and free from contamination or 4 weeks frozen once at -20°C. Anti-TG is stable for 3days at +2°C to +8°C. C-Peptide, IGF-I and Procalcitonin are stable for 1day at +2°C to +8°C. Osteocalcin is stable for 4 hours at +2°C to +4°C. Parathyroid hormone (PTH) should be tested within 4hours of reconstitution when stored at +2°C to +8°C, or within 2 weeks when stored below -20°C. Only the required amount of product should be removed. After use, any residual product should not be returned to the original vial.
Unopened: Store refrigerated (+2°C to +8°C). Stable to the expiration date printed on individual vials.

9. SUMMARY OF VALUE ASSIGNMENT

Each batch of Immunoassay Speciality I Control is submitted to a number of reference laboratories and values are assigned from a consensus of results obtained by these laboratories using a unique statistical analysis. With each batch a control range is provided for individual parameters and each parameter method. Average values should normally fall within the listed range for analytes specified in the product insert. However, variations may be caused by instrument, reagent, and laboratory technique. Therefore ranged provided here in should only be considered as a reference and it is recommended that each laboratory establish its not ranges.

10. TRACEABILITY

ANALYTE	SUPPLIER	PRODUCT NUMBER	ORIGIN	SOURCE
1-25 OH Vitamin D	Sigma	D-1530	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
25-OH Vitamin D	Sigma	H-4014	Synthetic Analytical Grade chemical	Commercial source, added volumetrically
Anti TG	Access Biologicals	Received under lot number	Human Plasma	Commercial source, added volumetrically
Anti TPO	Access Biologicals	Received under lot number	Human Plasma	Commercial source, added volumetrically
C-Peptide	Sigma	C-4999	Human Peptide	Commercial source, added volumetrically
IGF 1	Scipac	P264-0	Expressed in E.coli	Commercial source, added volumetrically
Insulin	Sigma	I-0259/I-2643	Human recombinant	Commercial source, added volumetrically
Osteocalcin	Anaspec/Sigma	22831/0-5761	Human Bone	Commercial source, added volumetrically
Procalcitonin	Randox	RCP9522	Extracted and purified from E.coli	Commercial source, added volumetrically
Parathyroid Hormone (PTH)	Sigma	P-7036	Human Thyroid	Commercial source, added volumetrically

11. CONCLUSION

Testing results indicate that the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2013

RANDOX LABORATORIES LTD.
C/O Ms. PAULINE ARMSTRONG
QA/RA MANAGER
55 DIAMOND ROAD
CRUMLIN CO ANTRIM BT29 4QY
UNITED KINGDOM

Re: K130337
Trade/Device Name: Immunoassay Speciality Control (I) levels 1, 2 and 3
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: April 12, 2013
Received: May 20, 2013

Dear Ms. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph. D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130337

Device Name: Immunoassay Speciality Control (I) Levels 1, 2 and 3

Indications For Use:

The Randox Immunoassay Speciality Control (I) Levels 1, 2 and 3 are intended for in vitro diagnostic use as assayed quality control material to monitor the precision of laboratory testing procedures for 1-25 Dihydroxy Vitamin D (1-25 (OH)2 Vitamin D), 25 Hydroxy Vitamin D (25 OH Vitamin D), Anti-Thyroglobulin (Anti TG), Anti-Thyroid Peroxidase (Anti TPO), C-Peptide, Insulin Like Growth Factor (IGF 1), Parathyroid Hormone (PTH), Procalcitonin and Insulin.

This device is for prescription use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k130337